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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------------|
| 10/612,285 | 07/03/2003 | Richard Derek Iggo | 604-689 | 5824 |
| 23117 7590 08/23/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | EXAMINER PRIEBE, SCOTT DAVID | |
| | | | ART UNIT 1633 | PAPER NUMBER |
| | | | MAIL DATE 08/23/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/612,285

Applicant(s)

IGGO ET AL.

Examiner

Scott D. Priebe, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

The oath or declaration remains defective for the reasons of record set forth in the Office action of 1/3/07. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

Applicant has indicated in the reply of 7/3/07 that a corrected declaration will be submitted.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-11, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation “the endogenous left hand inverted terminal repeat (ITR) transcription factor binding sites” in lines 7-8. There is insufficient antecedent basis for this limitation in the claim. Deletion of “the” from this phrase would be remedial.

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Claims 1-3, 5-11, 21 and 22 remain rejected under 35 U.S.C. 112, second paragraph, for the reasons of record set forth in the Office actions of 3/7/06 and 1/3/07 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the number of human or animal transcription factor binding sites to those inserted as substations in ... E1A open reading frame" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim. The claim does not indicate that binding sites are "inserted with the E1A open reading frame".

Claim 1 recites the limitation "the adenovirus E1A open reading frame" in line 5. There is insufficient antecedent basis for these limitations in the claim. Insertion --of the wild type adenoviral DNA sequence-- following "frame" would provide the antecedent basis.

Claim 8 recites the limitations "the E4 promoter" and "the E1A enhancer" in line 2. There is insufficient antecedent basis for these limitations in the claim.

Applicant's arguments filed 7/3/07 have been fully considered but they are not persuasive. Applicant indicates that the amendments have overcome the previous grounds of rejection. In response, the amendments have overcome some, but not all, of the grounds of rejection.

Claim Rejections - 35 USC § 102

Claims 1, 3, 7, 9-11, 21, and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Iggo et al., WO 00/56909 for the reasons of record set forth in the Office action of 7/11/05.

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Applicant's arguments filed 7/3/07 have been fully considered but they are not persuasive. Applicant merely asserts that the claimed invention is not suggested by Iggo and E1A is not mechanistically "directly" involved in viral replication. In response, regulation is part of the mechanism. Also, Iggo explicitly teaches modifying the E1A and E1B promoters with the transcription factor binding sites, which not excluded by the amended claims.

Claim Rejections - 35 USC § 103

Claims 1, 3, 7, 9-11, 21, and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., US 6,197,293 in view of Iggo et al., WO 00/56909.

Applicant's arguments filed 7/3/07 have been fully considered but they are not persuasive. Applicant states that "[N]either of the references discloses or suggests E1B control with wild type E2 or E3 and relocation of packaging signal". Without responding to the accuracy of this statement, the claims do not require such limitations, and the relevance of the statement is therefore unclear.

Double Patenting

Claims 1-3, 5-11, 21, and 22 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 7, 9, 11-16, 19, 20, and 25-38 of copending Application No. 10/433,681 for the reasons of record set forth in the Office action of 7/11/05. The claims as amended in the instant and copending applications are directed to the same disclosed embodiments, although the claims do not precisely match in scope.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has acknowledged the rejection but has declined to address it until prosecution has otherwise been completed in the two applications. Applicant is reminded of recent changes to procedures involving provisional obviousness-type double patenting rejections involving copending applications, see MPEP 804, subsection I.B.1. In a situation like this one, a proper provisional rejection in the junior application may not be withdrawn so long as the senior application is pending, even if junior application is otherwise in condition for allowance, but the senior application is not.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott D. Priebe/

Scott D. Priebe, Ph.D.
Primary Examiner
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